



UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office

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| SERIAL NUMBER | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---------------|-------------|----------------------|---------------------|
|---------------|-------------|----------------------|---------------------|

08/604,950 02/22/96 FRANCOIS

M JAB-948

12M2/0815

AUDLEY A CIAMPORCERO  
ONE JOHNSON AND JOHNSON PLAZA  
NEW BRUNSWICK NJ 08933-7003

REAMEXAMINER

ART UNIT PAPER NUMBER

1205

DATE MAILED: 08/15/96

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice of Draftsman's Patent Drawing Review, PTO-948. |
| 3. <input checked="" type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.      | 4. <input type="checkbox"/> Notice of Informal Patent Application, PTO-152.       |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1 to 8 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1 to 8 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with Informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved; ☐ disapproved (see explanation).
12. ☒ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

**Part III DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

2. Claims 1 to 8 are rejected under 35 U.S.C. § 103 as being unpatentable over Hoestetler et al in combination with Heeres et al(AI) and Heeres et al(A). The instant cyclodextrin and antifungal agent inclusion composition is taught by Hoestetler et al. The two secondary references teach oral preparations which show the additional ingredients in the instant composition to be conventional. The substitution of the cyclodextrin complex of

Hoestetler et al for the active ingredient into the compositions of the two secondary references to produce a more stable formulation is considered obvious given the teaching of Hoestetler et al. The determination of the pH of the formulation which produces the best results is considered to be easily determinable by one skilled in the art.

***Claim Rejections - 35 USC § 112***

3. Claims 1 to 8 are rejected under 35 U.S.C. § 112, first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any person skilled in the art to make and use the same, and/or for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is support in the specification for a limited number and type of cyclodextrin carriers with a limited number of antifungal agents. The specification does not give sufficient teaching to enable one skilled in the art to produce formulations with any other type of cyclodextrin and antifungal agent than those of claim 3. The alcohol co-solvent should also be limited to that which is supported in the specification since the use of propylene glycol with water appears to be essential to the formulation.


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**Conclusion**

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Reamer whose telephone number is (703) 308-4461.

  
JAMES H. REAMER  
PRIMARY EXAMINER  
GROUP 120 - ART UNIT 1205

JHR  
August 9, 1996